#16B

I hereby certify that this correspondence is being deposited with the United States Postal Service on the date set forth below as First Class Mail in an envelope addressed to: Commissioner for Patents, P O Box 2327, Arlington, VA 22202.

Date of Signature and Deposit: June 11, 2002

Nicholas J. Seay

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Frederick R. Blattner
Valerie Burland
Debra J. Rose
George F. Mayhew
Nicole Perna
Robert D. Perry
Susan C. Straley
Jacqueline D. Fetherston
Luther E. Lindler
Gregory V. Plano

Date: June 11, 2002

Serial No.: 09/409,800

Group Art Unit: 1655

Filed: 09/30/99

Examiner: Juliet Caroline Einsmann

Title: PLASMID DNA FROM YERSINIA PESTIS

File No.: 960296.95939

RESPONSE

Commissioner For Patents
P O Box 2327
Arlington, VA 22202

Dear Sir:

In response to the Office Action dated December 11, 2001 in the file of this application, please amend the application as follows:

In the Specification:

Page 1, line 7, delete the paragraph which begins "This invention" and insert therefor the following paragraph:

--This invention was made with United States government support awarded by NIH Grant No. HG01428, Subcontract No. 144 FH33. The US government has certain rights in this invention.--

B1

Page 37, line 18, delete Table 4 and replace it with the following:

--TABLE 4

Gene ID	Coords.	Genpept	Gi#match	Description of Match
Y0002	971>1165	gi|455143	RNA I	inhibition modulator protein (rom)
Y0003	1532>1903	gi|144312	ORF	[Plasmid ColE1]
Y0004	2389>2826	gi|1200166|gnl|PID|e223344		pesticin immunity protein [Yersinia pestis]
Y0005	2861<3934	gi|984824		pesticin [Yersinia pestis]
Y0006	4052>4468			unknown
Y0007	4711>5649	gi|155525		plasminogen activator [Yersinia pestis]
Y0008	5836<6135	gi|1806206|gnl|PID|e293663		unknown [Mycobacterium tuberculosis]
Y0009	6135<6482			unknown
Y0010	7312<7686			unknown
Y0011	7743>8765	gi|1655837	ORFA;	putative transposase [Yersinia pestis]
Y0001	8762>9544	gi|1655838	ORFB;	putative transposase [Yersinia pestis]--

Page 15, please amend the paragraph beginning on line 17 as follows:

Subsequent searches of the Swiss Protein, *E. coli* and non-redundant GenBank databases were obtained over the Internet using BLAST software (Altschul, et al., Nucleic Acids Res. 25:3389-3402, 1997) from the National Center for Biotechnology Information homepage (which can be found on the world wide web under ncbi.nlm.gov/BLAST). Pairwise protein alignments were with the BLAST algorithm. Protein localization was predicted for relevant translated *orf*s using the PSORT program (Nakai, et al. Proteins: Structure, Function, and Genetics 11:95-110, 1991). The prediction of membrane associated helices was with the TMpred program (Hoffman, et al. Biol. Chem. 347:166-172, 1993). Where appropriate, multiple protein sequences were aligned using the algorithm developed by Lipman *et. al.*(Proc. Natl. Acad. Sci. USA 86:4412-4415, 1989). These programs can be found as part of Pedros Molecular Biology Tools at Internet site www.iastate.edu.

In the Claims:

Please withdraw Claims 1-8 as non-elected, please amend Claims 9 and 10 as follows, and add the following new Claim 12:

9. (Amended) An isolated polynucleotide sequence having the sequence of SEQ ID NO:3, nucleotides 2389 to 2826, as found in plasmid pPCP1 found in *Yersinia pestis*.

10. (Amended) A recombinant DNA construction comprising an open reading frame placed under the control of a non-native promoter, the open reading frame being SEQ ID NO:3, base pairs 2389 to 2826, as found in *Yersinia pestis* plasmid pPCP1.

11. A host transformed with the DNA construction of claim 10.

12. (New) An isolated polynucleotide sequence comprising a DNA molecule of at least 25 continuous nucleotides contained in SEQ ID NO:3, nucleotides 2389 to 2826, or the complement to such 25 continuous nucleotides.

REMARKS

By an Office Action dated December 11, 2001 in the file of this application the Patent and Trademark Office Examiner rejected this application on a variety of grounds. Through this response, the applicants respond to each one of these grounds of rejection.

First, the Examiner has persisted in the requirement that the applicants elect a single nucleotide sequence for examination in this patent application. The applicants still contend that this requirement is unduly restrictive and inappropriate. The applicants believe that, at a minimum, they should have been permitted to elect all of the open reading frames contained in the plasmid pPCP1. The Examiner's restriction and requirement that the applicants elect a single species is unduly restrictive, burdensome, and not in accordance with the Patent Office practice or rules which have existed to this date.

Nevertheless, in order to avoid non-compliance with the Examiner's rejection, the applicants reaffirm their election of Group III and the specific open reading frame Y0004.

The Examiner has pointed to various informalities in the specification. These informalities have been corrected above.

In the first rejection of the claims in this application, the Examiner objected to Claims 9-11 under §112, second paragraph, on the grounds that the designation Y0004 is arbitrary. The Examiner requested that the applicants use a sequence identifier. Accordingly, the applicants have revised the claims to utilize the format preferred by the Examiner.

The other rejection made under §112, first paragraph, against the claims of this application was that they were overbroad, since they encompassed non-elected subject matter. The applicants still believe that they should have been entitled to obtain examination of the other subject matter. Nevertheless, in the interest of moving prosecution on the merits on the elected subject matter along, the applicants have temporarily withdrawn such subject matter from Claims 9-11. The only subject matter encompassed in those claims right now is the elected subject matter.

The Examiner also rejected Claims 9 and 10 under §101 because the claimed invention was not supported by credible utility. The applicants assert this is incorrect. These open reading frames are taken from the very plasmids which confer pathogenicity on the

human pathogen *Yersinia pestis*. It is an inescapable conclusion that these open reading frames are associated with, and probably necessary for, human disease caused by this organism. As such, the creation of proteins from these open reading frames, and the investigation of the open reading frames for possible candidates for prophylactic or therapeutic value are logical outgrowths of the research described in this patent application. This is sufficient utility for patent purposes.

Please note that it is also specifically recited that this DNA is useful for diagnostic purposes. Contained within the specification of this application at pages 11 to 13 thereof, is a specific recitation of how this DNA information may be used to diagnostically determine whether a particular sample contains the pathogenic organism in question, *Yersinia pestis*. As such, the DNA sequences have diagnostic utility, and this rejection is believed poorly framed.

In the context of the rejection under §101, the Examiner also applies this same rejection for non-utility against Claim 9. Again the applicants state that Claim 9 describes DNA which has diagnostic utility to diagnose the presence or absence of *Yersinia pestis* in a sample. This is patentable utility.

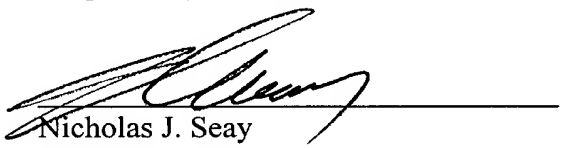
The first rejection applied against the claims was to Claim 9-11 under 35 U.S.C. §102(b) as anticipated by Rakin et al. The undersigned has examined the sequence contained in Rakin et al., Figure 2, and is unable to match that sequence to the sequence specifically claimed in the remaining claims in this patent application. Applicants acknowledge that Rakin seems to assign a title to the protein that matches the tentative identification by the applicants, but the DNA sequences claimed are not the same, at least in the undersigned's comparisons. Since the claims have been limited now specifically to nucleotide sequences claimed by sequence number, whatever designation Rakin et al. uses for their DNA is not important. Rakin does not have the same sequence, and a rejection under 102 is inappropriate.

Last in the Office Action is a rejection under §102(a) over a publication by Hu et al. Submitted with this response is a Declaration of Valerie Burland intended to establish that the invention claimed in this patent application was in the hands of the applicants prior to the publication date of the Hu et al. paper. Accordingly, this Declaration should be sufficient

under the provisions of 37 C.F.R. §1.131 to remove Hu et al. as a reference against the claims of this patent application. Accordingly, it is believed that this rejection is overcome.

Wherefore a reconsideration of the merits of this patent application is respectfully requested. A petition for extension of time is submitted herewith so that this response will be considered as timely filed.

Respectfully submitted,



Nicholas J. Seay
Reg. No. 27,386
Attorney for Applicants
QUARLES & BRADY LLP
P O Box 2113
Madison, WI 53701-2113

TEL 608/251-5000
FAX 608/251-9166